



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,355	12/03/2003	Ih-Jen Su	12563-020001	5446
26161	7590	11/09/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			SHIN, DANA H	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,355

Applicant(s)

SU ET AL.

Examiner

Dana Shin

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9-9-2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-26 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 19, 2006.

Accordingly, claims 1-42 are pending and claims 27-41 pertaining to SEQ ID NO:3 are currently under examination on the merits.

Specification

The abstract of the disclosure is objected to because it contains an incomplete sentence. See line 1, which recites "An RNA molecule for inhibiting expression of a gene of a virus.", which is a fragment, not a complete sentence. Correction is required. See MPEP § 608.01(b).

The title of the invention, "Antivirus RNA", is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 27, 30, 32, 35, 37, and 40 are objected to for containing non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and /or chemical properties, functional characteristics, structure/function correlation, or any combination thereof.

In the instant case, the breadth of claims 27-41 is so broad that it reads on any structure of a DNA vector comprising a nucleic acid such as a vector comprising an antisense oligonucleotide, a vector comprising an siRNA, a vector comprising a ribozyme, a vector comprising a DNAzyme, and so forth. Although the specification discloses anti- HBV siRNA vectors comprising SEQ ID NO:1-10, the siRNA vectors are not representative of the structurally defined genus recited in the claims. With the exception of the siRNA vectors comprising SEQ ID NOs:1-10, the skilled artisan cannot envision the detailed chemical structure of the recited DNA vector containing a nucleic acid and therefore conception is not achieved until reduction to

Art Unit: 1635

practice has occurred, regardless of the complexity or simplicity of the method of reducing the expression/replication of a virus. Since the instant specification provides adequate description of siRNA vectors only, it is concluded that the inventors were only in possession of siRNA vectors of the claimed genus of the DNA vector containing a nucleic acid.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991), which clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (see page 1117).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 32, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “comprising introducing into the cell an effective amount of the RNA of claim 1” in line 2. Since the claims, as written, depend from a non-elected claim, claim 1, the

Art Unit: 1635

claims are considered indefinite. For claim interpretation purpose, the claims will be construed to depend from “comprising introducing into the cell an effective amount of a DNA vector containing a nucleic acid encoding the RNA”. In that case, the limitation “the RNA” in line 3 lacks antecedent basis in the instant claims.

Claims 27-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims, claims 27, 32, and 37 recite “a DNA vector containing a nucleic acid encoding the RNA” in lines 2-3. Further, claims 30-31, 35-36, and 40-41 recite the phrase “the segment contains”. It is unclear and ambiguous whether the term “contain” means an open-end transitional phrase such as “comprise” or a closed-end transitional phrase such as “consist of”. Since neither the claim itself ^{nor} of the instant disclosure adequately describes the term “contain”, one skilled in the art cannot ascertain the metes and bounds set forth by the claims. For claim interpretation purpose, the term “contain” will be construed as “comprise” in light of the broadest reasonable interpretation of the claim language, which is consistent with MPEP §2111.03.

Claims 30-31, 35-36, and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "the segment" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-29 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (*Journal of General Virology*, 1997, 78:641-647).

The claims are drawn to a method of reducing a hepatitis B virus expression/replication in a cell comprising introducing a DNA vector containing a nucleic acid sequence encoding the HBV.

Wu et al. teach a method of reducing/inhibiting HBV infection and expression comprising introducing antisense HBsAg RNA expression vectors in a human hepatoma cell line. See "Methods" section on page 642. They show inhibitory effects of the antisense HBsAg by demonstrating the reduced level of HBV mRNA expression in the antisense RNA expression

Art Unit: 1635

cells and the reduced level of the HBV surface antigen (HBsAg), which persist for 10 months in the antisense HBsAg RNA vector-transfected cells. See pages 644-645.

Accordingly, the teachings of Wu et al. anticipate all the elements of the instantly claimed invention.

Claims 27-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Morrissey et al. (US 2003/0206887 A1).

The claims are drawn to a method of reducing a hepatitis B virus expression/replication in a cell and a method of treating a HBV infection in a subject comprising introducing a double-stranded RNA, wherein the RNA contains SEQ ID NO:3.

Morrissey et al. teach SEQ ID NO:712 (19-mer), which is perfectly complementary to the instant SEQ ID NO:3. They also teach SEQ ID NO:66 (19-mer), which is an RNA form of the instant SEQ ID NO:3. They further teach SEQ ID NO:1378 (21-mer), of which nucleotides 3-21 are perfectly complementary to the instant SEQ ID NO:3 and SEQ ID NO:1301 (23-mer), of which nucleotides 1-19 perfectly align with the instant SEQ ID NO:3, wherein T's are replaced with U's. See Table II. They teach that a double-stranded RNA molecule comprising any one of SEQ ID NO:712, 66, 1378, and 1301 or an expression vector comprising any one of SEQ ID NO:712, 66, 1378, and 1301 can be used to modulate the expression /replication of a HBV gene in a cell and to treat human hepatitis B virus infections (paragraphs 0044, 0046-0047, 0053, 0118, and 0275-0276).

Accordingly, the teachings of Morrissey et al. anticipate all the elements of the instantly claimed invention.

Claims 27-29, 32-34, and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Kay et al. (US 2003/0139363 A1, also applicant's citation No. AA, Form PTO-1449, filed on September 9, 2004).

The claims are described above.

Kay et al. teach a method of reducing viral gene expression/replication and a therapeutic method of reducing viral infection comprising administering a DNA vector encoding an siRNA or shRNA in a mammalian cell, wherein the viral gene is selected from HBV, HCV, HIV, influenza A, Hepatitis A, poliovirus, enteroviruses, rhinoviruses, and aphthoviruses (paragraphs 0011, 0039, 0046, 0048, 0052-0053, 0081, 0086). In particular, Kay et al. teach a method of inhibiting hepatitis B virus replication in mice by administering an HBVU6 RNAi plasmid vector, wherein 6 out of 7 shRNA expression plasmids effectively reduce the amount of HBsAg compared to the empty vector control. See paragraphs 0228-0245.

Accordingly, all the limitations of the instantly claimed invention are taught by Kay et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

JZ
T-1600
JANE ZARA, PH.D.
PRIMARY EXAMINER